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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,912	01/30/2004	Carl Ernest Alexander	4506-1025	2239
⁴⁶⁵ YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			<div>EXAMINER</div> <div>ROBERTS, LEZAH</div> <div>ART UNIT</div> <div>PAPER NUMBER</div> <div>1612</div> <div>MAIL DATE</div> <div>DELIVERY MODE</div>	
			11/13/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,912

Applicant(s)

ALEXANDER ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 7-18 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-9, 13 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to the amendment filed July 15, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

Claims 1-6 and 13 were rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 2002/0048553). The rejection is maintained in regards to claims 1, 3-5 and 13 and further applied to claims 23-26. Claims 2 and 6 are cancelled.

Applicant's Arguments

Applicant argues the reference does not teach a homogenous and non-encapsulated single dose gel bead comprised of an active ingredient intimately mixed with at least one gelling agent. The capsules and particles comprise a covering and the flavoring is injected into the gelatinous shell casing. The capsules and particles form cavities within the capsules to be filled with ingredients. The reference clearly teaches

the jelly-like material and the other contents of the capsule and/or binding particles as distinct, separate components. This argument is not persuasive.

Examiner's Response

The reference discloses the particles as a capsule and/or particle. The capsules have coating. The particles are free of a covering. It cannot be concluded that the Figure referred to by Applicant represents both the particle and capsule when the disclosure of the reference associates the covering directly to the capsule and not the particle. The reference also discloses the capsule is broken open (paragraph 0023). It does not make this statement in regards to the particle. There is also no reference to the particle forming a cavity as argued by Applicant. Further the particle is made of a thixotropic gel and possibly of an active agent (paragraph 0012). The reference also discloses components such as coloring are in the particles made of binding agent whereas in regards to the capsules, the coloring is in the capsule wall. It can be concluded that the particle has a drug or coloring mixed within the binding material, therefore meeting the limitations of the amended claims. In regards to the single dose unit, the particles are in toothpaste which is a single dose unit when applied to a toothbrush or the teeth.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-2, 5-9 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Alexander (WO 2002/026078, English Equivalent 2004/0091431). The rejection is maintained in regards to claims 1, 5, 7-9 and 13, and further applied to claims 23, 26 and 27. Claims 2 and 6 are cancelled.

Common Owner ship in view of 103 (c)

Applicant asserts the secondary reference Alexander and the instant application, at the time the invention was made, is commonly owned. Therefore the obviousness rejection is improper according to 35 USC 103 (c).

Examiner's Response

In regards to Applicant owning WO 2002/026078, the publication is an international publication with a publication date of April 4, 2002 making it available under 102(b) because it is before the foreign priority date, January 31, 2003, and more than a year before the US filing date, January 30, 2004. Therefore the rejection is proper.

Applicant's Arguments

Applicant argues neither Schmidt nor Alexander individually or in combination teaches or suggests all the features recited in claims 1 of the application. The Schmidt formulation is unsuitable in the shape of a bead. To roll up the strips to make a compact bead shape would result in too long a delay before it can be used in the mouth as a toothpaste. One of skill would readily understand that the outside of a bead made in this

manner would be in solution long before the inside starts to dissolve. This argument is not persuasive.

Examiner's Response

The compositions of the Schmidt are cast into films by applying them to a surface. Therefore it may be concluded that when forming a bead, the composition would be cast into a mold to form a bead and is not made by rolling up a strip as argued by Applicant. The mixture would still remain uniform as in the case of the strip with the only difference being the shape. When the outside is dissolved, the active agents are still released and therefor the composition will still function as a toothpaste. No matter the shape, it is reasonable to conclude the composition will perform the same. Further, Alexander discloses how to make a bead and it would have been obvious to one of skill to use these methods to make beads out of the composition of Schmidt.

Claims 1, 3-5, 7-9, 13 and 23-27 are rejected.

Claims 10-12 and 14-18 are withdrawn.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612